Proficiency Testing Survey Program

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1. Introduction:

Laboratories performing testing on clinical specimens must comply with the Clinical Laboratory Improvement Act (CLIA) regulations in order to maintain a certificate of compliance. The CLIA regulations provide standards on the following aspects of proficiency testing (PT):

- enrollment in an accredited PT programs and testing of samples
- successful participation
- evaluation of performance on each testing event

These standards are contained in:

subpart H: Participation in proficiency testing for laboratories performing nonwaived testing, sections 493.801 through 493.865

subpart K: Quality System for nonwaived testing, sections 493.1230 and 493.1236

Laboratories certified in testing of food, environmental, forensic or animal samples must follow the regulations promulgated by their respective certification bodies.

2. Purpose:

This SOP outlines guidelines that will ensure compliance related to proficiency surveys and continued laboratory accreditation for laboratories accredited by Centers for Medicare and Medicaid Services (CMS) and /or The College of the American Pathologists (CAP).

Laboratories not accredited by CMA or CAP, may find this SOP as a good resource for establishing a PT program to monitor the testing in their specialties.

3. Scope:

This procedure applies to all clinical testing laboratories. For the clinical testing laboratories, this procedure encompasses proficiency testing for both regulated and unregulated analytes, as defined by Centers for Medicare and Medicaid Services (CMS).

Laboratories not regulated by CMS, may participate in this program and are responsible for ensuring compliance with the respective accreditation regulations.

4. Responsibilities:

A. Quality Assurance Department (QA):

- Overall management of the proficiency survey testing program for the clinical testing laboratories accredited by CMS and/or CAP
- Orders proficiency testing surveys
- Compiles a shipping schedule for proficiency testing surveys ordered by QA and distributes the schedule to all laboratories and the Bacteriology Lab Office
- Surveys ordered by QA include: College of American Pathologists (CAP) American Association of Bioanalysts (AAB); AOAC; Wisconsin State Laboratory of Hygiene (WSLH)
- Tracks the results of testing events
- Compiles a list of contact people in each laboratory for the surveys and distributes this list to all laboratories and the Bacteriology Lab Office
- Reviews results from proficiency surveys
- If applicable, assists laboratories with corrective action documentation for failed proficiency testing events
- If applicable, assists Laboratory Supervisor with response to the accrediting or certifying agency for failed proficiency testing events
- If applicable, completes a Proficiency Testing Self Evaluation form
- Maintains file of proficiency testing survey analysis reports
- Serves as liaison with the PT survey organizations
- Annually review the PT survey sets available to the clinical testing laboratories. Based on these surveys, make recommendations for new or replacement survey sets to the Laboratory Division Directors

B. Bacteriology Lab Office Staff

- Receives proficiency surveys from CAP, AAB and WSLH for clinical testing laboratories
- Contacts designated Laboratory staff when proficiency surveys are received
- Tracks the receipt date for proficiency surveys

- Tracks the due date for PT survey results
- Faxes or mails proficiency survey results
- Notifies QA Manager or Director of any problems related to survey receipt or faxing of results

C. Laboratory Supervisors

- Responsible for ensuring compliance with proficiency testing regulations
- Upon notification by the Bacteriology Lab Office staff, ensures that proficiency surveys are promptly picked up and delivered to the laboratory for testing.
- Tracks the receipt date for proficiency surveys
- Ensures that proficiency surveys are analyzed promptly and within the timeline specified for the survey
- Ensures that proficiency survey results and additional paperwork are verified prior to submission
- Ensures that proficiency samples are tested in the same manner that clinical or environmental specimens are tested
- When applicable, ensures that the proficiency survey result form to be faxed is delivered to the Bacteriology Office before the deadline date
- In instances when results are completed close to or on the deadline date, contacts the Bacteriology Office to make arrangements to ensure the results will be faxed by the close of business
- Reviews the proficiency survey analysis report and if applicable responds to failed proficiency event by identifying problems and taking corrective actions to prevent recurrence of similar problems
- Maintains the original testing worksheets and result form
- Notifies the QA Manager of problems related to unacceptable survey specimen condition or delays in testing PT survey specimens.
- Identifies a designee to take responsibility for PT surveys during an absence.
- Notifies the QA Manager of any additional PT surveys that the laboratory performs

D. Laboratory Division Directors

- Responsible for ensuring compliance with proficiency testing regulations
- For CAP surveys, signs the Attestation statement before results are faxed or mailed.
- Identifies a designee to sign the CAP Attestation statement during an absence.
- Annually reviews the available list of PT surveys and recommends revisions to the PT survey order as appropriate.
- Reviews PT survey results.
- Notifies the QA Manager of problems related to the PT surveys

E. Laboratory Director

- Responsible for ensuring compliance with the proficiency testing regulations
- Responsible for reviewing and signing all proficiency testing surveys

5. Related Documents

QA.009 Corrective Actions

6. Definitions:

AIHA
American Industrial Hygiene Association

Analyte
a substance or constituent for which the laboratory conducts testing

Approved accreditation program
a private, nonprofit accreditation organization that has formally applied for and received CMS's approval based on the organization's compliance with this part

CAP
The College of American Pathologists

Challenge
For quantitative test: an assessment of the amount of substance or analyte present or measured in a sample. For qualitative test: the determinations of the presence or absence of an analyte, organism, or substance in a sample

CLIA
Clinical Laboratory Improvement Act; code of federal regulations 42 CFR Part 493

CMS
Centers for Medicare and Medicaid Services

DEP
Department of Environmental Protection

ELPAT
Environmental Lead Proficiency Analytical Testing

HHS
Department of Health and Human Services

Nonwaived test
any test system, assay, or examination that has not been found to meet statutory criteria

specified in section 353(d)(3) of the Public Health Service Act; must meet all of the CLIA requirements for testing; all testing at HSLI is moderately complex and nonwaived;

Referee laboratory
a laboratory currently in compliance with applicable CLIA requirements, that has a record of satisfactory proficiency testing performance for all testing events for at least one year for a specific test, analyte, subspecialty or specialty and has been designated by an HHS approved proficiency testing program as a referee laboratory for analyzing proficiency testing specimens for the purpose of determining the correct response for the specimens in a testing event for that specific test, analyte, subspecialty or specialty

Regulated analyte
Nonwaived test for which proficiency testing is required by CLIA

TVR
Transmission verification report for fax transmissions

Unregulated analyte
Test for which proficiency testing is not required by CLIA

Unsatisfactory proficiency testing performance
Failure to attain the minimum satisfactory score for an analyte, test, subspecialty or specialty for a testing event

Unsuccessful participation in proficiency testing means any of the following:
(1) Unsatisfactory performance for the same analyte in two consecutive or two out of three testing events. (2) Repeated unsatisfactory overall testing event scores for two consecutive or two out of three testing events for the same specialty or subspecialty. (3) An unsatisfactory testing event score for those subspecialties not graded by analyte (that is, bacteriology, mycobacteriology, virology, parasitology, mycology, blood compatibility, immunohematology, or syphilis serology) for the same subspecialty for two consecutive or two out of three testing events. (4) Failure of a laboratory performing gynecologic cytology to meet the standard at §493.855.

Unsuccessful proficiency testing performance
a failure to attain the minimum satisfactory score for an analyte, test, subspecialty, or specialty for two consecutive or two of three consecutive testing events

WSLH
Wisconsin State Laboratory of Hygiene

7. Procedure

A. Enrollment in proficiency testing (PT) surveys

Each laboratory must enroll in PT surveys in order to maintain accreditation or licensure for testing. PT surveys for CLIA accredited laboratories must be purchased from CLIA approved PT providers.

When PT surveys are not available from CLIA approved PT providers, surveys may be purchased from commercial PT companies as long as they meet the CLIA requirements for the number of testing events and the number of challenges per testing event, as a minimum.

An additional option of preparing an in house blinded panel may be exercised when a commercial survey can not be identified. The in house blinded panel must also meet the CLIA requirements for the number of testing events and the number of challenges per testing event, as a minimum. See section D.2. for specific guidance that will ensure consistency throughout HSLI between CLIA approved PT surveys and in house blinded panels.

Results for in house panels must be documented to include the following information:

1. date tested
2. name of testing personnel
3. test performed
4. expected result
5. actual result
6. score for the testing event
7. signature of the Laboratory Supervisor
8. signature of Laboratory Manager, if applicable
9. signature of the Laboratory Division Director

B. PT contact list and PT survey shipping schedule

The QA department will update the PT contact list and shipping schedule annually and as changes warrant. These lists will encompass PT surveys for the clinical laboratories that are purchased and the AOAC survey for the Foodborne Surveillance laboratory. These lists will be distributed to the Laboratory Division Directors, Laboratory Supervisors, and the Bacteriology office.
In house PT surveys are due to be completed and results submitted to the QA Office by the following dates: March 31; July 31; and November 30.

C. Distribution of PT survey materials

1. AAB, CAP and WSLH surveys only

a. Bacteriology Office staff

1. The Bacteriology Office staff receives AAB, CAP and WSLH Survey material.

The Bacteriology Office staff will stamp the date of receipt on the line provided by the these survey providers.

2. In the CAP notebook, stamp the receipt date in the Received Date column of the Proficiency Survey Shipping Schedule (Attachment #1). The AAB, CAP and WSLH survey forms will indicate a deadline for the results. Write this date in the Deadline date column of the Proficiency Survey Shipping Schedule. (If the survey states number of days to the result deadline, do not count the date of receipt as the first day.) If a deadline date line is provided on the survey result form, write the deadline in that space as well.
3. Make one copy of page 1 of the Survey Result Form. Refer to the contact list for proficiency surveys and call the person listed as the 1st contact to let him/her know that the survey is received and ready to be picked up. If after 2 attempts, there is no response to the phone call, call the 2nd contact person on the list. On the copy of page 1 of the Survey Result Form, document your name, the date, time and name of each person called.
4. In some years, surveys from CAP are shared by multiple labs. When surveys are shared, make two copies of the complete result form and the instructions. The labs will determine when these surveys are to be shared, based on the specimens contained in the survey set. After making copies of the result forms, call the person listed as the 1st contact for that survey.
5. Once the survey material is picked up by someone in the laboratory, verify the result deadline date with the person picking up the survey. If there is a discrepancy on the due date, clarify the actual due date before the person leaves with the survey. On the copy of page 1 of the Survey Result Form, document the name of the person who receives the survey, and the time and date of receipt.
6. File the copy of page 1 of the Survey Result Form in the CAP notebook.
7. If a survey set is not received within 2 days of the expected shipping date, notify the QA manager. The QA manager will contact the PT survey organization. The QA manager will document all information regarding this survey and the replacement survey on the master tracking form in the Bacteriology Office. The QA manager will notify the laboratory supervisor of the alternate arrangements.

b. Laboratory Supervisors

1. Once the Bacteriology Office staff notifies you of the receipt of the proficiency survey, ensure that you or a designee promptly reports to the Bacteriology Office to pick up the survey. Verify the result deadline date with the Bacteriology Office staff. If there is a discrepancy on the due date, clarify the actual due date before leaving.
2. If a survey set is not received within 2 days of the expected shipping date, notify the QA manager. The QA manager will contact the PT survey organization. The QA manager will document all information regarding this survey and the

replacement survey on the master tracking form in the Bacteriology Office. The QA manager will notify the laboratory supervisor of the alternate arrangements.

NOTE: Leaking Survey Materials

1. Outside of the package is visibly contaminated upon receipt in the Bacteriology Office:
    a. The Bacteriology Office staff must notify the nearest laboratory technician, supervisor or manager of the leaking package. The Bacteriology Office staff must not handle the leaking package.
    b. The laboratory technician, supervisor or manager must remove the package from the office area and disinfect the desk or counter.
    c. Anyone who handled this package should immediately wash his/her hands in one of the laboratories.
    d. Once it is determined which survey set was received, notify the QA Manager. The QA Manager will call the PT provider to inform them of the damaged set and to request new specimens. When new specimens are requested, ask when these specimens will be shipped, the expected receipt date and when the results are due.
    e. All of the information regarding the leaking package and the information about the replacement specimens must be documented in the PT survey book which is kept in the Bacteriology Office and be communicated to the Laboratory Supervisor.

2. Specimens inside the package are damaged or leaking upon receipt in the laboratory:
    a. The lab technician or supervisor will handle this as they would any other biological spill.
    b. Once the spill is cleaned up, the Laboratory Supervisor must notify the QA Manager of the damaged specimens.
    c. The QA Department will call the PT provider to inform them of the damaged set and to request new specimens. When new specimens are requested, ask when these specimens will be shipped, expected receipt date and when the results are due.
    d. All of the information regarding the leaking package and the information about the replacement specimens must be documented in the PT survey book which is kept in the Bacteriology Office and be communicated to the Laboratory Supervisor.

2. AOAC surveys

AOAC sends an email notification to the QA manager of the shipping date 3 – 5 days prior to the shipping date. The QA manager forwards the email notification to the Laboratory Division Director and Laboratory Supervisor for the Foodborne Surveillance laboratory. Upon receipt in the Receiving Department, the survey materials are delivered directly to the laboratory.

The technician in the laboratory receiving the survey material will write the receipt date and time in the space provided on the AOAC form. The technician in the lab must notify the Bacteriology Office Staff when the survey is received in order to document the receipt date on the master list.

3. Other surveys

Additional surveys are received by various labs from many different PT providers. Each laboratory takes responsibility for enrolling in the surveys, and receiving the surveys.

D. Testing PT samples

1. PT surveys from outside companies

Laboratory Supervisors are responsible for ensuring the proper testing of the PT samples by taking responsibility for the following actions:

a. ensure that samples are tested with the laboratory's regular workload by personnel who routinely perform testing, using the laboratory's testing methods;
b. when a PT sample requires special handling, document any special handling on the worksheets; examples may include reconstitution of a sample, conversion of the units of measure;
c. test PT samples the same number of times that the lab routinely tests patient samples;
d. document handling, preparation, processing and each step in testing and reporting;
e. do not send any portion of PT samples to another laboratory for any reason;
f. do not contact another laboratory regarding the testing of or result of a PT sample;
g. report incident to Laboratory Director, if another laboratory sends a PT sample or contacts the laboratory about the testing or results of a PT sample;
h. review worksheets and results before completing the proficiency survey form;
i. complete the appropriate response fields on the proficiency survey result form and verify the entries;
j. have all technicians involved in any phase of testing the survey samples sign the appropriate worksheets. For CAP, have the technicians and the Laboratory Director or designee sign the Attestation Statement. If a technician is not present to sign the Statement, print the technician's name on the testing personnel page and initial the entry. If the Laboratory Director is not present to sign the Statement, have the Director's designee sign the Statement. For the AOAC surveys, list all technicians names on the line provided on the result form;
k. for survey results that are mailed, make a copy of the entire report form for your laboratory files.

2. PT samples for in house PT surveys

In house PT surveys will be developed and tested in the following situations:

- an unregulated analyte is being tested
- there is no CLIA approved PT survey
- there is no commercially available PT survey

For an in house PT survey, the Supervisor will:

a. ensure that three testing events are performed and that each testing event contains at least five challenges;
b. ensure that samples are tested with the laboratory's regular workload by personnel who routinely perform testing, using the laboratory's testing methods;
c. ensure that when a PT sample requires special handling, that any special handling is documented on the worksheets; examples may include reconstitution of a sample, thawing of a sample;
d. ensure that the technician tests PT samples the same number of times that they routinely test patient samples;
e. blind the samples;
f. prepare an answer key;
g. prepare a document containing the sample identifiers, the name of the testing analyst, the date of testing, the analyte tested, the expected results, the actual results obtained on the PT sample and a score for the testing event;
h. ensure that the PT document is submitted to QA by the last day of March, July and November.

E. Submitting Results to the Bacteriology Office

1. AAB, CAP, WSLH

a. Bacteriology Office Staff

1. Three (3) days prior to the result due date, call the 1st contact person to remind him/her of the due date. If after 2 attempts, there is no response to the phone call, call the 2nd contact person on the list.
   If the Laboratory Supervisor informs the Office staff that the results will only be ready on the result due date, have him/her speak to the Bacteriology Office Supervisor. If the Bacteriology Office Supervisor is absent, contact one of the Managers of the Bacteriology Laboratories, located in the same office area. The Office Supervisor and the Laboratory Supervisor will make arrangements to ensure that the results will be faxed either by the Office staff or the Laboratory Supervisor on the due date.
2. When the laboratory brings the final result form to be faxed or mailed, verify that the Laboratory Director and the Testing personnel have signed the Attestation Statement for the CAP surveys.
3. If this statement is not signed, call the person who brought the result form to the office and have that person obtain the proper signatures before the form is faxed.
   NOTE: If the Director is not available to review and sign, then the Director's designee may review and sign the Attestation Statement.

b. Laboratory Supervisors

1. Bring the result form and the fax number or self addressed envelope for the results to the 4th Floor Bacteriology Office. If noone is in the area, there are several options: (1) leave the result packet in the wall mounted holder labeled "Fax Proficiency Survey" ; (2) bring the results back to the Office later in the day.
2. If the results for the survey will not be ready for transmission until the due date, as soon as possible, contact the 4th Floor Office at extension 6600 to ensure that the results will be faxed by either the Office staff or the Laboratory Supervisor on the due date. If the 4th Floor Office Staff is unavailable, contact the QA manager for assistance.
   If the Laboratory Supervisor takes responsibility for faxing the results, use the fax machine in the 4th Floor Bacteriology Office. After the fax transmittal is completed, date and initial the transmittal verification report (TVR) and make a copy of the TVR and page 1 of the Survey Result Form. Place the original TVR and the copy of page 1 of the result form in the mailbox labeled "PT survey faxed", which is located just inside of the 4th Floor Bacteriology Office. The Supervisor faxing the results will keep the copy of the TVR
3. Report any problems with the proficiency survey (sample integrity, delayed receipt, delayed result reporting) to the QA Director or QA Manager.

2. AOAC

The Foodborne Surveillance laboratory will notify the Bacteriology Office staff when results are submitted electronically to AOAC.

F. Submitting Results to the PT Provider

1. CAP, WSLH via FAX transmission

NOTE: Fax transmissions

If there are black streaks on the transmission verification report (TVR), the fax machine needs to be serviced and the results must be refaxed. Black streaks on the TVR indicate a problem with the fax transmission. The Bacteriology Office staff will service the fax machine on the 4th floor.

a. Once all of the paperwork is in order, fax the entire result form to the Fax number provided on the result form. For CAP survey results, follow the specific CAP faxing instructions for the proper settings on the fax machine. For WSLH survey results, follow the specific WSLH faxing instructions.

b. Once the Fax is completed:
   1. initial the Transmission Verification Report (TVR) and make a copy of the

TVR
2. staple the copy of the TVR to the original CAP, or WSLH result form
3. call the contact person from the laboratory to pick up the result form and the TVR
4. place the copy of the TVR and Survey Result Form in the wall mounted holder marked "PT surveys faxed"
5. place the original TVR in the office CAP Notebook and staple it with the copy of page 1 of the Survey Result Form

c. Report any problems with the receipt of result forms from the laboratory by the due date or any fax transmission problems to the QA Manager.

d. Document the date of the fax transmission in the Result Date column of the Proficiency Survey Shipping Schedule.

2. AAB – results mailed

a. Bacteriology Office staff
1. Confirm with the laboratory representative that the lab made a copy of the entire result form for their files.
2. If all paperwork is in order, place all result forms in the mailing envelope and prepare for mailing.
3. Report any problems with the receipt of result forms from the laboratory by the due date to the QA Director or QA Manager.
4. Document the date the results are placed in the mail in the Result Date column of the Proficiency Survey Shipping Schedule.

b. Laboratory Supervisors

If the results for the survey will not be ready for mailing until the due date, as soon as possible, contact the Bacteriology Office at extension 6600 to ensure that the results will be mailed by either the Office staff or the Laboratory Supervisor on the due date. If the Bacteriology Office Staff is unavailable, contact the QA Manager. In situations when a laboratory will not have the results prepared by the deadline date, the Laboratory Supervisor will be responsible for mailing the results, and for notifying the 4th Floor Bacteriology Office Staff of the date the results were mailed.

3. Electronic submissions

Surveys which typically fall into this category include surveys from the CDC, the Laboratory Response Network, NY State, AIHA ELPAT, and DEP. These PT surveys

are delivered directly to the appropriate Laboratory Supervisor. The Supervisors must ensure that these samples are tested in accordance with the PT survey instructions and that results are submitted by the deadline.

G. Receipt of Results

PT results are received by the QA manager or the individual Laboratory Supervisor. The results of each testing event must be reviewed in a timely manner and the review must be documented. All surveys require the Laboratory Director's signature. Receipt and review of the results requires coordination between the QA manager and the Laboratory Supervisors and Laboratory Directors.

1. Results received in the QA Office

- The QA Manager logs survey and result of the testing event into the spreadsheet.
- The QA Manager reviews results to determine if a self evaluation form or a corrective action form is needed. See section (H) for self evaluations and section (I) for corrective actions. The spreadsheet is annotated if a self evaluation or corrective action is generated.
- If the survey was performed by more than one lab, the QA manager will ensure that signature lines exist for each Laboratory Supervisor, Laboratory Manager and Laboratory Division Director, as applicable.
- The QA Manager makes one copy of survey result report. The original document is sent to the appropriate Laboratory Supervisor, Laboratory Manager and Laboratory Division Director for review, comment and signatures. The copy of the document is filed in QA until the original is returned with the required signatures.
- Once the original document is signed by the appropriate Laboratory Supervisor(s), Laboratory manager(s), Laboratory Division Director(s) and returned to QA, the QA Manager delivers the document to the Laboratory Director for review and signature.
- After the Laboratory Director signs the document, the QA manager makes a copy for each laboratory that participated in the survey. The original document is filed in QA and the copies are delivered to the appropriate Laboratory Supervisors, Laboratory Managers or Laboratory Division Directors.

2. Results received in the Laboratory

- The Laboratory Supervisor, Laboratory Manager and Laboratory Division Director must review and sign the survey results. If the survey was performed by more than one

laboratory, the Supervisors and Division Directors from each of the laboratories must sign the same document.

- The Supervisors, Managers and Division Directors review the results to determine if a self evaluation form or a corrective action form is needed. See section (H) for self evaluations and section (I) for corrective actions. If a self evaluation or corrective action is required, contact the QA manager for the appropriate forms and tracking numbers.

- Once all of the documentation is completed, send the original document to the QA Manager.

- The QA Manager logs the survey and test event result into the spreadsheet and documents comments in the spreadsheet, as applicable.

- The QA Manager reviews the results, ensures that all signatures are present and then delivers the survey result document to the Laboratory Director for review and signature.

- After the Laboratory Director signs the document, the QA manager makes a copy for each laboratory that participated in the survey. The original document is filed in QA and the copies are delivered to the appropriate Laboratory Supervisors, Laboratory Managers or Laboratory Division Directors.

3. Results of in-house PT surveys

- The Supervisors, Managers and Division Directors review the results to determine if a corrective action form is needed. See section (I) for corrective actions. If a corrective action is required, contact the QA manager to obtain the appropriate form and tracking number.

- Once all of the documentation is completed, send the original document to the QA Manager.

- The QA Manager logs the survey and testing event result into the spreadsheet and documents comments in the spreadsheet, as applicable.

- The QA Manager reviews the results, ensures that all signatures are present and then delivers the survey result document to the Laboratory Director for review and signature.

- After the Laboratory Director signs the document, the QA manager makes a copy for the laboratory. The original document is filed in QA and the copies are delivered to the appropriate Laboratory Supervisors, Laboratory Managers or Laboratory Division Directors.

H. Evaluation of Results

PT survey results must be evaluated to determine which of the following categories describes the grading for the testing event:

1. Satisfactory performance: grade of 80% - 100%
2. Unsatisfactory performance: grade is less than 80%
3. Unsuccessful proficiency test performance: failure to attain minimum satisfactory score for two consecutive or two of three consecutive testing events
4. The testing event was not graded by the PT provider
5. Failure by the laboratory to participate in the testing event
6. Failure by the laboratory to submit the PT results to the PT provider within the specified deadline

The chart below provides guidance on documentation that may be appropriate for each situation. Since each testing event is unique, QA will discuss any grades of less than 100% and ungraded events with the laboratory Supervisor to determine the applicable actions to take and the appropriate documentation for the testing event.

Refer to section I: Surveys requiring a self evaluation and section J: Surveys requiring a corrective action.

Grade for event	Investigate	Self evaluation	Corrective action
100%			
80% - 99%	√		+/-
Less than 80%			√
Unsuccessful performance on two consecutive events			√
Testing event not graded		√	
Failure to participate	√	+/-	+/-
Failure to submit results by deadline		√	√

√ = action required +/- = action may be required blank cell = no action required

I. Surveys results requiring a self evaluation

To maintain compliance with the CLIA regulations, a self evaluation form must be completed when the following conditions exist:

1. The proficiency testing program does not obtain 80 percent of ten or more referee laboratories or 80 percent or more of all participating laboratories (42 CFR 493.1236(a));
2. The proficiency testing program does not evaluate or score results in instances of educational challenges and lack of consensus of results (42 CFR 493.1236(1));
3. The laboratory receives a zero score for nonparticipation, or late return of results. (42 CFR 493.1236 (2)).

When a self evaluation is required, the HSLI QA Self Evaluation form must be completed as outlined below.

1. Compare the laboratory's responses with the intended response of the proficiency testing program, if available or with the referee laboratory responses, if available, or the participant responses, if available.
2. Handwrite, date and initial the responses by the referee laboratories and/or the participants and/or the intended responses directly on the survey result form.
3. Complete the State Laboratory Quality Assurance Proficiency Testing Self Evaluation form. Refer to attachment C, CAP Guidance from the Participant Summary Booklet: Actions Laboratories Should Take when a PT Results is Not Graded.
4. The form must be signed by the QA Manager, Laboratory Supervisor, Laboratory Manager, Laboratory Division Director and the Laboratory Director.
5. The original will be filed in QA with the corresponding survey results.
6. A copy of the form will be distributed to the appropriate Laboratory Supervisor, Laboratory manager or Laboratory Division Director.

J. Survey results requiring a corrective action

When one or more survey results are unacceptable, a corrective action may be initiated. Additional reasons to generate a corrective action for PT surveys may include the following situations: survey results submitted after the deadline, testing survey samples was not in compliance with laboratory procedures, survey results form completed improperly. Refer to the table on page 16 for additional guidance.

The QA manager will issue the corrective action identification number and send a copy of the corrective action form (Attachment E) to the Laboratory Supervisor for completion. For additional information, refer to QA.009, Corrective Actions. The corrective action identification number must be documented on the survey results form and if applicable, the self evaluation form.

The QA manager will document the corrective action identification number in the PT

survey tracking spreadsheet and will monitor the completion of the corrective action plan via the corrective action spreadsheet.

Attachment D, AAB Guidance from the Proficiency Testing Service: Corrective Action Checklist Form, provides guidance on factors that should be consider or investigated and documented for any type of investigation or corrective action.

K. Distribution and Evaluation of the CAP Final Critiques

These documents are received after the results are published and the laboratory's performance has been graded. The QA office files the original in the PT survey binder and sends a copy to the appropriate Laboratory Supervisor or Laboratory Manager. The final critiques are reviewed by the Laboratory Supervisor, Laboratory Manager and the Laboratory Division Director.

8. Flow Diagram – Not applicable

9. Compliance Monitoring

The Laboratory Director, the Laboratory Division Director, the Laboratory Manager and the Laboratory Supervisor are responsible for monitoring compliance with the proficiency testing regulations for the individual laboratories.

The Quality Assurance Manager is available to assist with compliance monitoring and is responsible for maintaining a tracking spread sheet to monitor overall performance on the proficiency testing surveys.

10. Record Retention

The proficiency testing associated records are to be retained according to the current Massachusetts Statewide Record Retention Schedule. These records meet the current record definition of: K4-4: Health Laboratory test, clinical. The current record retention time is three years. In addition, records must be available for an entire inspection cycle. If a laboratory is inspected every two years, records for three full years ensure meeting this requirement.

11. References

42 CFR Part 493, Medicare, Medicaid and CLIA programs; Laboratory Requirements Relating to Quality Systems and Certain Personnel Qualifications; Final Rule

Subpart H: 493.801 through 493.865

Subpart K: 493.1230 and 493.1236

Participant Summary Booklet College of American Pathologists, Actions Laboratories Should take when a PT Result is not graded, 2008.

12. Attachments

A. Sample of the Proficiency Shipping Schedule
B. Self Evaluation Form
C. CAP Guidance from the Participant Summary Booklet: Actions Laboratories Should Take when a PT Results is Not Graded.
D. AAB Guidance from the Proficiency Testing Service: Corrective Action Checklist Form,
E. Hinton State Laboratory Corrective Action Form (2 parts)
F. Letter from CMS dated September 19, 2008: Proficiency Testing Referral – Risk of Severe Sanctions

Attachment #A Sample of the Annual Proficiency Shipping Schedule

Code	Survey name	Shipping date	Received date	Deadline	Result Date
E	CAP Mycobacteriology				
VM1	AABB/CAP Viral Markers – Series 1				
AOAC	AOAC Standard Microbiology M01				
HC6	CAP Chlamydia / GC by NAA				
D	CAP Bacteriology				
VR1	CAP Virology Culture				
ST	CAP Shiga toxin				
AAB	AAB Oral-Fluid HIV Antibodies				
BL	CAP Blood Lead				
VR3	CAP Virology Antibody Detect.				
VR3M	CAP Virology Antibody - Mumps				
RUB	CAP Rubella				
AHIV	CAP Anti HIV- 1 / 2				
D3	CAP GC Culture				
G	CAP Syphilis Serology				
ID1 **NEW**	CAP Nucleic amplification, Viruses				
ID2 **NEW**	CAP Nucleic amplification, Respiratory				

Attachment #B Proficiency Testing Self Evaluation

Laboratory:	**Survey date:**
Survey name / code:	

A. Reason for self evaluation:

☐ Specimen(s) not graded, lack of consensus ☐ Specimen(s) not graded, educational challenge ☐ Results not submitted within turn around time; *see corrective action*: _____

Explanation of reason for testing or reporting delay:

_____

☐ Other (Describe); *see corrective action*: _____

_____

B. Documentation of self evaluation: List specimens that require a self evaluation

☐ SLI response agrees with intended response
☐ SLI response doesn't agree with intended response; *see corrective action*_____

Spec. #	Analyte	SLI response	Intended response

Review

Laboratory Supervisor/ Manager / date:	Comments:
Laboratory Division Director / date:	Comments:
Quality Assurance / date:	Comments:
Laboratory Director / date:	Comments:

Attachment C. CAP Guidance from the Participant Summary Booklet: Actions Laboratories Should Take when a PT Result is Not Graded

Actions Laboratories Should Take when a PT Result is Not Graded

The College uses Exception Reason Codes for the proficiency testing (PT) analyte that has not been graded. The Exception Reason Code is located on the evaluation report in brackets to the right of the result. Identify all of the analytes with an Exception Reason Code and investigate the acceptability of performance with the same rigor as if it were an unacceptable performance. The actions accredited laboratories should take include but are not limited to:

Codes	*Exception Reason Code Description*	*Action Required*
11	Unable to analyze.	Document why the specimens were not analyzed (e.g., instrument not functioning or reagents not available). Perform and document alternative assessment (i.e., split samples) for the period that commercial PT was not tested to the same level and extent that would have been tested.
20	No appropriate target/response; cannot be graded.	Document that the laboratory performed a self-evaluation using the" all-instrument" data presented in the Participant Summary. Perform and document this review.
21	Specimen problem.	Document that the laboratory has reviewed the proper peer group statistics supplied by the PT Provider. Perform and document alternative assessment for the period that commercial PT was not tested to the same level and extent that would have been tested. Credit is not awarded in these cases.
22	Result is outside the method/ instrument reportable range.	Document the comparison of results to the proper peer group statistics and peer group information supplied by the PT Provider. Verify detection limits.
24	Incorrect response due to failure to provide a valid response code.	Document the laboratory's self-evaluation against the proper peer group statistics supplied by the PT Provider. Perform and document the corrective action of any unacceptable results. Document corrective action to prevent future failures.
25	Inappropriate use of antimicrobial.	Document the investigation of the result as if they were unacceptable and review the proper reference documents to gain knowledge of the reason your response is not appropriate.
26	Educational challenge.	Response to the CAP is not required. Laboratory should document its review.
27,31	Lack of participant or referee consensus.	Document that the laboratory compared its results to the modal (most common) result. Perform and document this review.
28	Response qualified with a greater than or less than sign; unable to quantitate.	Document the laboratory's self-evaluation against the proper peer group statistics supplied by the PT Provider. Verify detection limits.
30	Scientific Committee decision.	Document that the laboratory has reviewed the proper peer group statistics supplied by the PT Provider.
33	Specimen determined to be unsatisfactory after contacting the CAP.	Document that the laboratory has contacted the CAP and no replacements specimens were available. Perform and document alternative assessment (i.e., split samples) for the period that commercial PT was not tested to the same level and extent that would have been tested.
40	Results for this kit were not received.	Document why results were not received, corrective action to prevent recurrence and the laboratory's self-evaluation of the results by comparing results to the proper peer group statistics supplied by the PT Provider.
41	Results for this kit were received past the evaluation cut-off date.	
42	No credit assigned due to absence of response.	The Participant Summary booklet mailed with the proficiency testing evaluation indicates which tests are graded (see evaluation criteria) and which tests are Not Evaluated/Educational. Updates to grading will also be noted. If a test is educational, the laboratory is not penalized for leaving a result(s) blank. The code 42 that appears on the evaluation is **not** a penalty. *However, if a test is graded (regulated and non-regulated analytes) and your laboratory performs that test, results cannot be left blank. The laboratory is required to submit results for **all** challenges within that test or use an appropriate exception code or indicate test not performed/not applicable/not indicated. Exceptions may be noted in the Kit Instructions and/or the Result Form. Document corrective actions to prevent future failures.*
44	This drug is not included in our test menu. Use of this code counts as a correct response.	Verify that the drug is not tested on patient samples and document to ensure proper future reporting.
77	Improper use of the exception code for this mailing.	Document the identification of the correct code to use for future mailings.
91	There was an insufficient number of contributing challenges to establish a composite grade.	Document the investigation of the result as if it were an unacceptable result. Perform and document the corrective action if required.
*35, 43, 88, 92	Various codes.	No action required by the LAP.

3 Rev 2/2009

D. AAB Guidance from the Proficiency Testing Service: Corrective Action Checklist Form

CORRECTIVE CHECKLIST FORM

This form is offered solely as a guide to assist investigating, documenting and correcting proficiency test failures. No representations are made by AAB concerning the effectiveness of the checklist. It is the responsibility of the laboratory to identify the reasons for failure in proficiency testing and to take appropriate corrective measures. AAB does not guarantee that performance of this self-check will affect future success regarding proficiency testing. This document is for internal laboratory use and is NOT to be submitted to AAB.

1.	**SPECIMEN HANDLING**		
	a. Were proficiency test specimens checked for acceptability when received? (Review notes made at time proficiency test was performed.)	☐ Yes	☐ No
	b. Were the specimens handled properly? (Review instructions for specimen preparation.)	☐ Yes	☐ No
2.	**CLERICAL ERRORS**		
	a. Verify correct value was transcribed from instrument printout to report form, or that the correct response was entered from the list of results.	☐ Yes	☐ No
	b. Verify that decimal point and units of measure were honored on report form.	☐ Yes	☐ No
	c. Verify that the correct code from the instrument or reagent list was entered on report form.	☐ Yes	☐ No
	d. Verify that the correct testing method information was provided.	☐ Yes	☐ No
	e. Check summary report to verify value on report form was honored by PT service.	☐ Yes	☐ No
3.	**QUALITY CONTROL**		
	a. Were controls in range on date of PT?	☐ Yes	☐ No
	b. Any evidence of trending, shifting in periods just before and just after PT?	☐ Yes	☐ No
4.	**CALIBRATION**		
	a. Date of last calibration?	☐	
	b. How often is calibration performed?	_____	
	c. When was last calibration verification performed?	_____	
	d. Were any calibration problems noted?	☐ Yes	☐ No
5.	**INSTRUMENT**		
	a. Were instrument parameters entered correctly?	☐ Yes	☐ No
	b. Was daily maintenance performed on date of proficiency testing?	☐ Yes	☐ No
	c. Was special maintenance performed just prior to proficiency testing?	☐ Yes	☐ No
	d. Were instrument problems noted when proficiency testing was performed?	☐ Yes	☐ No
6.	**REAGENTS**		
	a. Checked reagent/instrument log for notation of recent problems.	☐ Yes	☐ No
	b. Checked reconstitution instructions in insert versus procedure—any changes?	☐ Yes	☐ No
	c. Verified that open stability of reagent was not exceeded by reviewing procedure with testing personnel.	☐ Yes	☐ No
7.	**TESTING PERSONNEL**		
	a. Date of last competency assessment for testing personnel.	☐	
	b. Reviewed assay procedure and proficiency test sample preparation instructions with testing personnel to ensure that instructions were followed.	☐ Yes	☐ No
	c. Reviewed with testing personnel how samples were loaded to rule out misidentification or transposition of samples.	☐ Yes	☐ No
8.	**PROCEDURE**		
	a. Reviewed procedure versus manufacturer's most current recommendations for any changes.	☐ Yes	☐ No
	b. Called instrument or reagent manufacturer for input if cause was not readily identified.	☐ Yes	☐ No
9.	**INTERPRETATION ERRORS**		
	a. Was PT challenge beyond the scope and extent of the testing routinely performed in your lab?	☐ Yes	☐ No
	b. Has summary report been reviewed for an explanation of key features of the element presented in the photomicrographs?	☐ Yes	☐ No
	c. Have textbook references been consulted for additional information?	☐ Yes	☐ No
	d. (Microbiology) Compare the test characteristics found in your laboratory with the characteristics of the correct identification. Review your results and procedures for the key to distinguish the correct identification from the incorrect identification.	☐ Yes	☐ No

E. Hinton State Laboratory Corrective Action Form

Corrective Action Form
Description and Action Plan

ID # Event Date: Dept.:

1. Identification of nonconformity or quality problem:

Recorded by: Date:

2. Investigation:

Recorded by: Date:

3. Action plan:
a. Short term:

b. Long term:

Recorded by: Date:

4. Review

Laboratory Division Director / date: _____
Comments:

Quality Assurance Manager / date: _____
Comments:

Quality Assurance Director / date: _____
Comments:

Corrective Action Form
Implementation and Outcomes

ID# Event Date: Dept.:

☐ Short Term ☐ Long Term

1. Implementation of Changes (include description of change, date of change)

Recorded by: Date:

2. Follow-up and Outcomes (Were the changes effective or do they need to be re-assessed?)

Recorded by: Date:

3. Additional Comments

Recorded by: Date:

4. Review

Laboratory Division Director / date: _____
Comments:

Quality Assurance Manager / date: _____
Comments:

Quality Assurance Director / date: _____
Comments:

Laboratory Director / date: _____
Comments:

F. Letter from CMS dated September 19, 2008: Proficiency Testing Referral – Risk of Severe Sanctions

CMS
CENTERS for MEDICARE & MEDICAID SERVICES

Center for Medicaid and State Operations

September 19, 2008

CLIA ID: 22D0650270

WILLIAM A HINTON STATE LABORATORY INSTITUTE
305 SOUTH STREET
JAMAICA PLAIN MA 02130-3515

SUBJECT: Proficiency Testing (PT) Referral – Risk of Severe Sanctions

Dear Laboratory Director,

The Centers for Medicare & Medicaid Services (CMS) has recently experienced an increase in occurrences of improper PT referral. Therefore, we wish to convey the strongest possible encouragement for laboratories to:

A. Examine their internal processes to ensure maximum integrity of the proficiency testing process in their laboratory;

B. Promote laboratory-wide employee training in the CLIA requirements to process PT samples in the same manner as patient specimens;

C. Avoid any inter-laboratory communications regarding PT samples during the PT event; and

D. Promote laboratory awareness that PT samples or parts of samples should never be referred to another laboratory for any reason

These requirements should be of particular concern to Laboratory Directors, as they are ultimately responsible for laboratory compliance, and will be held accountable in accordance with the CLIA regulations in instances where non-compliance is found. In the remarks below, we discuss in more detail the importance of avoiding a PT referral in your laboratory and the mandatory penalties that ensue when PT referral occurs.

Every PT referral is subject to serious sanction. The Public Health and Service Act at section 353(i)(4) requires the revocation of a laboratory's CLIA certificate if it is found to have made an improper PT referral. This refers to PT mandated by CLIA regulations and when PT is used to meet the accuracy requirements for unregulated analytes. It provides:

"(4) IMPROPER REFERRALS – Any laboratory that the Secretary determines intentionally refers its proficiency testing samples to another laboratory for analysis shall have its certificate revoked for at least one year and shall be subject to appropriate fines and penalties as provided for in subsection (h)."

Subsection (h) sanctions have particular impact on laboratory owners and operators. Subsection (h)(3) reads in pertinent part:

"No person who has owned or operated a laboratory which has had its certificate revoked may, within 2 years of the revocation of the certificate, own or operate a laboratory for which a certificate has been issued under this section..."

The CLIA regulations as 42CFR Part 493.801(b)(3) and (4) indicate that laboratories must not engage in any inter-laboratory *communications* pertaining to the results of PT samples and the laboratory must not *send PT samples* or *portions of PT samples* to another laboratory for analysis.

If your laboratory refers PT samples or a portion of PT samples to another laboratory, you risk the revocation of your CLIA certificate and the required sanctions against the laboratory owner and director. There have been numerous hearing decisions from the U.S. Department of Health and Human Services (DHHS), Departmental Appeals Board (DAB), upholding the citation of deficiencies and mandatory sanctions imposed upon a laboratory when there is a determination of improper PT referral.

The consequences of improper PT referral are so serious that I urge you to take the time to ensure that your laboratory has effectively designed and implemented proper PT policies and procedures to guard against improper PT referral and assure that all laboratory personnel are trained accordingly.

To assist you in preventing these occurrences, I have included a list of Frequently Asked Questions (FAQ) on this topic.

For any questions you may have concerning this letter please refer to the CMS CLIA web site for more information on PT at www.cms.hhs.gov/clia/.

I very much appreciate your prompt attention to the issues described here.

Judith A. Yost
Director, Division of Laboratory Services
Survey and Certification Group

Attachment: FAQs

CMS
CENTERS for MEDICARE & MEDICAID SERVICES

Center for Medicaid and State Operations/ Survey and Certification Group

IMPORTANT INFORMATION FOR NON-WAIVED LABS

FREQUENTLY ASKED QUESTIONS ABOUT CLIA REQUIREMENTS FOR PROFICIENCY TESTING (PT)

NOTE: This information applies to CMS inspected laboratories. If your laboratory is accredited, you MUST follow the proficiency testing requirements of your accreditation organization, but should be aware of CLIA requirements. This does not apply to cytology PT.

What is proficiency testing?
Proficiency testing or PT is the testing of unknown samples sent to a laboratory by a CMS approved PT program. Most sets of PT samples are sent to participating laboratories three times per year. After testing the PT samples in the same manner as its patient specimens, the laboratory reports its sample results back to their PT program. The program grades the results using the CLIA grading criteria and sends the laboratory scores reflecting how accurately it performed the testing. CMS and accreditation organizations routinely monitor their laboratories' performance.

Why is PT important?
PT is important because it is a tool the laboratory can use to verify the accuracy and reliability of its testing. Routine reviews of PT reports by the laboratory staff and director will alert them to areas of testing that are not performing as expected and also indicate subtle shifts and trends that, over time, would affect their patient results.

If I only perform waived testing, am I required to perform PT?
PT is not required for any test that is waived. (Check the FDA web site to determine whether your test(s) are waived: www.FDA.gov/cdrh/CLIA.) However, enrolling in a PT program and performing PT on your waived test(s) will provide you with an excellent indication of the accuracy of the waived test(s) and thus improve the quality of testing you provide to your patients. It also serves to demonstrate the accuracy of your testing if it is ever questioned.

Is PT required for all nonwaived testing?
PT is required for only the limited number of tests found in Subpart I, Proficiency Testing Programs for Nonwaived Testing, of the CLIA regulations in 42CFR Part 493. If your laboratory performs any of the tests found in subpart I, you must perform PT on each of the tests. We refer to the tests listed in subpart I as "regulated" analytes. Review the specialty, subspecialty and analytes listed and determine which specialties, subspecialties and analytes you perform in your laboratory. Enroll in a CMS approved PT program for each of those tests. A listing of these tests may be found on the last page of the FAQ.

Can I enroll in any program that offers PT?
You must enroll in a CMS approved PT program. A detailed listing of these programs with their contact information and the tests for which they are approved is available at www.cms.hhs.gov/clia, and click on "PT providers".

What must I do to enroll in PT?

Using the list on the CLIA web site, choose one (more than one, if your director wishes) of the approved PT program(s) that offer(s) the tests you perform in your laboratory. The PT program will assist you with your enrollment if you ask. The program will notify CMS of your enrollment and the PT testing you have signed up to perform. If you enroll in more then one PT program for a single test, you must designate to the PT provider which one is for CLIA compliance purposes.

How do I enroll for bacteriology? Must I enroll for five PT samples for each test I do in bacteriology; Gram stain, direct antigen, identification of organisms, and/or susceptibility testing?
Your laboratory must enroll for a total of five PT samples per testing event and those five samples must include at least one of the types of testing your laboratory performs – Gram stains, direct antigen, identification of organisms, and/or susceptibility testing. If you perform one or two of these procedures, the five samples must include the one or two tests you perform. Call your PT program; the PT representatives will help you enroll properly. Assisting you with proper enrollment is a CLIA requirement for approved PT programs.

If I have more than one testing site, do I need to enroll in PT for each site?
PT enrollment and participation is required for each CLIA certificate i.e., PT per certificate (excluding certificate of waiver). If you offer non-waived testing at more than one site, but the testing is all included under one certificate, you must enroll in an approved PT program(s) for all the "regulated" analytes covered under that certificate, not for each site. If you have a separate certificate for each site, you must enroll in PT for all regulated tests performed at each site.

May I change my PT program whenever I wish as long as it is CMS approved?
You may not randomly change from one approved PT program(s) to another. Laboratories must enroll and participate in one approved program for one year before designating a different program. Laboratories should enroll in the fall for the next calendar year. However, if you apply for a new CLIA certificate mid-year or add a "regulated" specialty, subspecialty, or analyte in the middle of a year, you may change PT programs at the next PT enrollment period.

If my laboratory is new or if I add a new "regulated" specialty, subspecialty or analyte in the middle of a calendar year, how quickly must I enroll in PT?
Laboratories operating under a new certificate and/or adding new "regulated" testing must enroll in PT as soon as possible and complete the PT for the remainder of the year.

If I perform "unregulated" testing (tests for which PT is not required), am I required to check the accuracy and reliability of those tests?
CLIA requires laboratories to take steps to assure the accuracy of testing in lieu of testing PT samples. CLIA requires that, at least twice annually, you verify the accuracy of any test or procedure that you perform that is not listed in Subpart I. PT may be used to meet this requirement, if available.

How do I verify the accuracy of the tests that do not have PT required?
A few examples of ways to check the accuracy of testing not listed in Subpart I are as follows:

- Split a patient's specimen (**NEVER SPLIT A PT SAMPLE**) with another laboratory that offers the same test(s). Your director should review your results and the other laboratory's results for acceptability.
- Perform PT on the tests (many PT programs offer a limited number of PT samples for "unregulated" tests), but **NEVER** send the PT samples out of the laboratory for any reason. Depend on the scoring by the PT program to determine accuracy.

Are there ever circumstances in PT that require my laboratory to verify the accuracy of "regulated" tests?

Yes there are. There are times when the PT program cannot fully evaluate your samples and you must verify accuracy (a few ways to accomplish this are listed above). You must verify the accuracy of tests for which PT is required if any of the following occur:

- When your results are submitted to the program after the deadline and are considered a late submission, your laboratory grade will be zero.
- If you did not test your PT samples at all, your laboratory grade will be zero.
- When your grade does not reflect your performance because there was no consensus among all laboratories performing the PT sample(s), you will see this identified by the PT program as "ungradable" on your results report. You will be assigned an artificial score of "100%", noted as "ungradable", but that does NOT reflect your performance, so you will need to check accuracy.

Do I test my PT samples any differently than I test patient specimens?
PT samples must be tested in the same manner you test patient specimens. This means testing the PT samples the same number of times as patient specimens, at the same time as patient specimens, by the same personnel that routinely test the patient specimens, and using the same test system that is routinely used for the patient specimens. PT samples should be rotated among the testing personnel in your laboratory.

Please note that some PT sample preparation may be necessary before testing. In other words, after preparation, PT samples must be treated in the same manner as patient specimens. However, as stated below, **NEVER** send PT samples out of your laboratory for any reason, even if you routinely send out patient specimens for additional or confirmatory testing.

May I discuss my PT results with another laboratory?
NEVER discuss your PT results with another laboratory and **NEVER** enter into discussion with another laboratory about their PT results before the PT event cut-off date. This activity may cause you to lose your CLIA certificate.

May I send my PT samples to another laboratory to see if they get the same results as I do?
NEVER send your PT samples to another laboratory even if you send your patient specimens to another laboratory for confirmation or identification testing. (Please read the PT results sheet carefully and select "Would refer" or "Test not performed" in these instances.) Sending PT samples to another laboratory for testing is considered PT referral and will cause serious actions to be taken against your laboratory, your laboratory director, and the laboratory owner. The penalties include loss of your laboratory's CLIA certificate for at least one year, your director cannot direct a laboratory for two years, and your laboratory owner may not own or operate a laboratory for two years.

Your laboratory's name will be listed on the CMS Laboratory Registry on the CMS web site.
Be extremely cautious **NOT** to send PT samples out for a "reflex" test. (A "reflex" test is a test procedure routinely added-on to a patient specimen when the test results are at a level that meets the clinician's threshold to automatically add specific tests. This is usually done by a "standing" order.)

What do I do if I receive PT samples from another laboratory for testing?
As soon as you identify them as PT samples, notify your inspecting agency (your accreditation organization if your laboratory is accredited or your State agency inspectors) that you have received PT samples from another laboratory, tell them the name of the other laboratory and the test(s) requested, but DO NOT TEST the samples.

Do I need to keep records of my PT testing?

Yes, you must keep a copy of all your records, such as the step by step PT sample preparation and handling, all the steps taken in the testing of the sample, a copy of the PT program results form used to record and submit your PT results (includes the attestation statement), a print screen if results are entered electronically, and the PT program's evaluation of your laboratory's performance, etc. These copies must be maintained for a minimum of two years from the date of the PT event. If any corrective actions are taken as a result of an unsatisfactory or unacceptable score, maintain records of these actions for two years also.

If I perform the same test using two different test systems, must I perform PT on both test systems?
PT is required for only the test system, assay, or examination used as the primary method for patient testing during the PT event.

How long do I have to test and report the PT samples?
The instructions that accompany the PT samples will state the exact date by which you must return your PT results to the program. It is very important to return them on time. A late submission will result in a score of zero for the testing event.

What steps should I take after I have received my PT results from the PT program?
Always review your results with your co-workers and your director. Your PT program will include an evaluation for each of the five challenges for each test or analyte in the PT event and will detail the performance of each test system used by the laboratories enrolled with their program.
This should be done for all PT results, even those with passing scores. If you receive an 80% score, you should investigate why one of the five samples was outside the acceptable range of results. Document your investigation and what you did to correct the problem that caused the challenge failure.

What must I do if I do not get a passing score when the PT program grades my results?
Re-review the results that were submitted to the PT program for scoring for any obvious errors (this should have been done prior to submitting your results to the program). Clerical or transcription errors are considered incorrect results. The director of your laboratory as well as the personnel who performed the testing of the PT samples should compare their PT results with the inter-laboratory comparison evaluations provided by the PT program. You must take remedial actions, i.e., determine the cause of the error or errors, correct it (them), and document your actions. Continually monitor the test system performance, review the results of the quality control materials, and discuss with your director to be certain the test system is operating properly and producing accurate results. Your director may want to review the results of the patients tested during the unsatisfactory or unacceptable testing event. Depending upon the test system's performance and your director's decision, you may need to contact the manufacturer of the test system for assistance.

What does unsatisfactory PT performance mean?
Unsatisfactory PT performance means failure to attain the minimum satisfactory score for an analyte, test, subspecialty, or specialty for a testing event. Clerical errors are considered a failure.

****What does unsuccessful participation in PT mean?***
Unsuccessful participation in PT means any of the following:

- Unsatisfactory performance for the same analyte in two consecutive or two out of three testing events.
- Repeated unsatisfactory overall testing event scores for two consecutive or two out of three testing events for the same specialty or subspecialty.

- An unsatisfactory testing event score for those subspecialties not graded by analyte (that is, bacteriology, mycobacteriology, virology, parasitology, mycology, compatibility testing, unexpected antibody detection, antibody identification) for the same subspecialty for two consecutive or two out of three testing events.

What does unsuccessful PT performance mean?
Unsuccessful PT performance means a failure to attain a satisfactory score for an analyte, subspecialty, or specialty for two consecutive or two of three consecutive testing events.

*Please note – unsuccessful performance and unsuccessful participation are interchangeable. CMS inspectors generally will use unsuccessful performance.

If I do not successfully participate in PT, what happens?
If your laboratory has never had an unsuccessful performance for any PT analyte, subspecialty, or specialty, the CLIA regulations, under certain circumstances, permit technical assistance and training to take place, rather than a more serious sanction. However, repeated unsuccessful PT performance for that same analyte, subspecialty or specialty may result in your laboratory no longer being allowed to perform the failed testing.

My laboratory has been required to cease testing an unsuccessful analyte, subspecialty, or specialty. What must I do to be able to resume testing?
First, you must demonstrate that your laboratory has identified the reason(s) for your unsuccessful performance and corrected it(them). Be sure to document this process. Secondly, when you are certain you have corrected the problem(s), your laboratory must perform two consecutive PT events (re-instatement PT) successfully, which will demonstrate correction of the problem(s).

If you have been required to cease testing, your Medicare and Medicaid reimbursement will be suspended for a six month period. However, you may purchase your re-instatement PT events at any time after you have identified and corrected the problem(s) that caused the unsuccessful performance. You should purchase these samples from your PT program, but you may obtain them from any CMS approved PT program.

You may decide to voluntarily stop testing the unsuccessful analyte, subspecialty, or specialty. As soon as you receive your PT results indicating an unsuccessful performance, you must notify your regional office CLIA consultant that testing of the unsuccessful analyte, subspecialty, or specialty has been stopped voluntarily.

This notification must be made before you receive a letter from your CMS regional office imposing a cease testing sanction. You will need to successfully perform two consecutive PT events for the analyte, subspecialty, or specialty that was unsuccessful. Your Medicare and Medicaid reimbursement will not be affected.

Be sure to read the CLIA regulations for proficiency testing (available on the CMS web site). This FAQ is not intended to replace or be a substitute for the CLIA regulatory requirements. It is intended only to present most of the proficiency testing requirements in layman's terms.

List of Nonwaived Testing for which PT is Required:

MICROBIOLOGY

Bacteriology
- Aerobic/Anaerobic Culture & Identification
- Antibiotic Susceptibility Testing
- Direct Bacterial Antigen Detection
- Gram Stain

Mycobacteriology
- Acid Fast Stain
- Mycobacteriology Identification
- Mycobacteriology Susceptibility Testing

Mycology
- Culture and Identification

Parasitology
- Presence or Absence of Parasites
- Identification of Parasites

Virology
- Direct Viral Antigen Detection
- Viral Isolation and Identification

DIAGNOSTIC IMMUNOLOGY

Syphilis Serology

General Immunology
- Alpha-1 Antitrypsin
- Alpha Fetoprotein (tumor marker)
- Antinuclear Antibody
- Antistreptolysin O
- Anti-Human Immunodeficiency Virus (Anti-HIV)
- Complement C3
- Complement C4
- Hepatitis B Surface Antigen (HBsAg)
- Hepatitis B Core Antibody (Anti-HBc)
- Hepatitis Be Antigen (HBeAg)
- Immunoglobulins, total:
  - IgA
  - IgG
  - IgM
  - IgE
- Infectious Mononucleosis
- Rheumatoid Factor
- Rubella

CHEMISTRY

Routine Chemistry
- Alanine Aminotransferase (ALT or SGPT)
- Albumin
- Alkaline Phosphatase
- Amylase
- Aspartate Aminotransferase (AST or SGOT)
- Bilirubin, total
- Blood Gases:
  - pH
  - pCO2
  - pO2
- Calcium, total
- Chloride
- Cholesterol, total
- Cholesterol, HDL
- Creatine Kinase, total
- Creatine Kinase, Isoenzyme (CK-MB)
- Creatinine
- Glucose
- Iron, total
- Lactate Dehydrogenase (LDH), total
- LDH Isoenzymes (LDH1/LDH2)
- Magnesium
- Potassium
- Sodium
- Total Protein
- Triglycerides
- Urea Nitrogen
- Uric Acid

Endocrinology
- Cortisol
- Free Thyroxine
- Human Chorionic Gonadotropin
- T3 Uptake
- Triiodothyronine
- Thyroid Stimulating Hormone
- Thyroxine, total

Toxicology
- Blood Alcohol
- Blood Lead
- Carbamazepine
- Digoxin
- Ethosuximide
- Gentamicin
- Lithium
- Phenobarbital
- Phenytoin
- Primidone
- Procainamide and Metabolite
- Quinidine
- Theophylline
- Tobramycin
- Valproic acid

HEMATOLOGY
- Cell Identification
- WBC Differential
- Erythrocyte Count
- Hematocrit
- Hemoglobin
- Leukocyte Count
- Platelet Count
- Fibrinogen
- Partial Thromboplastin Time
- Prothrombin Time

IMMUNOHEMATOLOGY
- ABO Group
- D (Rho) Typing
- Unexpected Antibody Detection
- Compatibility Testing
- Antibody Identification